

Docket No. ORT-1547-US-CIP

UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Rames M. Kanojia, et al.

Serial No.: 10/719,875

Art Unit:

Filed

: November 21, 2003

Examiner:

For

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Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the aboveidentified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

In accordance with §1.97(b), since this Information \boxtimes Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required. In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with | the first or second After Final Submission, therefore: Statement in Accordance with §1.97(e) (attached); or П Please charge Deposit Account No. 10the fee of \$180.00 as set forth in §1.17(p). In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is

accompanied by one of: .

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	· — —	es of each of the references listed on the
		PTO-1449 were filed on in USSN 10/307,735,
·	On December 2,	2002.
	☐ Copi	es of references listed on the attached Form PTC
	1449 are enclos	sed herewith EXCEPT THAT:
		In view of the voluminous nature of references
		[list as appropriate], and the likelihood that
		these references are available to the Examiner,
		copies are not enclosed herewith.
		If any of the foregoing publications are not
		available to the Examiner, Applicant will
		endeavor to supply copies at the Examiner's
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		es of only foreign patent documents and non-
		ure are enclosed in accordance with 37 CFR 1.98
	(a)(2). (The	U.S. patents and each U.S. patent application

publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i).

$\hfill\Box$ There are no listed references which are not in the English language.
The relevance of those listed references which are not in the English language is as follows:
Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.
Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/ORT-1547-US-CIP/JSK. This form is submitted in triplicate.

Respectfully submitted,

Reg. No. 33(,189

Attorney for Applicants

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-3711 DATED: May 28, 2004



PTO/S8/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
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Sheet 1 of 3

valid OMB control flumber.
10/719,875
11/21/2003
Ramesh M. Kanojia
ORT-1547-US-CIP

U.S. PATENT DOCUMENTS

	Cite	U.S. Patent Document				
Examiner Initials		Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		5,395,842	Α	Labrie et al.	03-07-1995	
		5,686,465	Α	Labrie et al.	11-11-1997	
		5,840,735	Α	Labrie et al.	11-24-1998	
		6,060,503	Α	Labrie et al.	05-09-2000	
		6,133,458	Α	Bell et al.	10-17-2000	·
		6,153,768	Α	Jo et al.	11-28-2000	
		-				

FOREIGN PATENT DOCUMENTS

	Cite	Foreign Patent Document Office ³ Number ⁴ KindCode ⁵		nt	Name of Patentee or	Date of Publication of Cited Document	Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
Initiale				ndCode⁵	Applicant of Cited Document	mm-dd-yyyy,		
		EP	0470310	. B1	Council of Scientific and Industrial Research	02-12-1992		
		GB	1094806			12-13-1967		
		IND	173337		Council of Scientific and Industrial Research	04-09-1994	Abstract	
		wo	93/10741	A2	Endorecherche Inc.	06-10-1993		
		wo	96/26201	A1	Endorecherche Inc.	08-29-1996		

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Application Number	10/719,875
Filing Date	11/21/2003
First Named Inventor	Ramesh M. Kanojia
Group Art Unit	
Examiner Name	
Attorney Docket Number	ORT-1547-US-CIP

		Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item	
xaminer's nitials*	Cite No. ¹	(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T'
		ALBERT, J.L. et al.: "Estrogen Regulation of Placental Alkaline Phosphatase Gene Expression in a Human Endometrial Adenocarcinoma Cell Line ¹ "; Cancer Research 50, 1990, pp. 3306-3310.	
		ALLAN, G.F. et al.: "An Ultrahigh-Throughput Screening Assay for Estrogen Receptor Ligands"; Analytical Biochem. 275, 1999, pp. 243-247.	
		BARAN-MARSZAK, M. et al.: "Nouvelle synthese de lla dehydrorotenone et d'autres rotenoides (*)"; No. 34., Manuscript date 21.7.70; pp. 191-198.	
		CORNIA, M. et al.: "OXYGEN HETEROCYCLES BY OXIDATION OF <i>ortho</i> -ALKYLPHENOLS. OXIDATION OF <i>ortho</i> -PROPENYLPHENOLS."; Gassetta Chim. Italiana, 107, 1977, pp. 299-304.	
_,		GRESE, T.A. et al.: "Structure-Activity Relationships of Selective Estrogen Receptor Modulators: Modifications to the 2-Arylbenzothiophene Core of Raloxifene"; J. Med. Chem. 1997, 40, pp. 146-167.	
		GRESE,T.A. et al.: "Synthesis and Pharmacology of Conformationally Restricted Raloxifene Analogues: Highly Potent Selective Estrogen Receptor Modulators"; J. Med. Chem. 1998, 41, pp. 1272-1283.	
		KHAN, K.Z. et al.: "Reaction of Dimethyl Sulphoxide & Acetic Anhydride with 3-Substituted 4-Hydroxycoumarins ^a "; Indian J. of Chem. Vol. 24B, 1985, pp. 42-46.	
		NICOLAOU, K.C. et al.: "Total Synthesis of Amphoteronolide B and Amphotericin B. 1. Strategy and Stereocontrolled Construction of Key Building Blocks"; J. Am. Chem. Soc. 1998, 110, pp. 4672-4685.	
		SAEED, A. et al.: "StructureActivity Relationship of Antiestrogens. Studies on 2,3-Diaryl-1-benzopyrans"; J. Med. Chem. 1990, 33, pp. 3210-3216.	
		SHARMA, A.P. et al.: "StructureActivity Relationship of Antiestrogens. Effect of the Side Chain and Its Position on the Activity of 2,3-Diaryl-2H-1-benzopyrans"; J. Med. Chem. 1990 33, 3216-3222.	

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Application Number	10/719,875				
Filing Date	11/21/2003				
First Named Inventor	Ramesh M. Kanojia				
Group Art Unit					
Examiner Name					
Attorney Docket Number	ORT-1547-US-CIP				

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item	
Examiner's nitials*	Cite No.1	(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
		SHARMA, A.P. et al.: "StructureActivity Relationship of Antiestrogens. Phenolic Analogues of 2,3-Diaryl-2H-1-benzopyrans"; J. Med. Chem. 1990, 33, pp. 3222-3229.	
		WELSHONS, W.V. et al.: "Stimulation of breast cancer cells in vitro by the environmental estrogen enterolactone and the phytoestrogen equol"; Breast Cancer Research and Treatment 10: 1987, pp. 169-175.	
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